K071929 SEP 19 2007

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

NAVITRACK® SYSTEM – PARTIAL HIP RESURFACING UNIVERSAL

Applicant: ORTHOsoft Inc.
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Contact Person: Christopher McLean

Date Summary Prepared: July 12, 2007

Device Trade Name: Navitrack® System – Partial Hip Resurfacing Universal

Device Classification Name: Stereotaxic Instrument (84 HAW); 21 CFR § 882.4560

Predicate Devices:

1) Vectorvision® Hip SR; from Brainlab, AG; 510(k) # K063028
2) Navitrack® System – Total Hip Replacement CT-Free; from Orthosoft Inc.; 510(k) # K032917
3) Navitrack® System – OS Knee Universal; from Orthosoft Inc; 510(k) # K060336

Device Description:

The Navitrack® System – Partial Hip Resurfacing Universal system consists of software, a computer workstation, an optical tracking system, surgical instruments, and tracking accessories, designed to assist the surgeon in the placement of partial hip resurfacing components.

Tracking devices are incorporated onto given surgical instruments and onto fixation bases attached to the femur by which the system tracks their relative locations and displays back to the user corresponding positional information intra-operatively to initially plan and then guide the positioning of the components.

The instruments that are tracked include a drill guide to help position the implant's system guide wire or pin that sets the central axis for the implants. The femoral reference geometries relative to which the guide wire location is to be positioned include representations of the femoral head and neck surfaces as rendered by clouds of points that are digitized by the user using the system.

In addition, the system also allows for specific implant models as obtained from the implant manufacturers to also be included in the system. In this mode, the system also displays the implant models relative to the bony geometries corresponding to the placement.

Indications for Use / Intended Use:
The Navitrack® System - Partial Hip Resurfacing Universal is indicated for use as a stereotaxic instrument to assist in the positioning of partial hip resurfacing components. It is a computer controlled image-guidance system equipped with a three-dimensional tracking sub-system. It is intended to assist in precisely positioning hip femoral resurfacing components intra-operatively by displaying their positions relative to the joint's alignment axes as based on user-identified anatomical landmarks.

Technological Comparisons to the Predicates:
The fundamental scientific technology of the predicates is unchanged. The main operating principle and control mechanism are maintained in the proposed device to similarly provide image guidance assistance in the placement of orthopedic implants. Secondary software and instrument engineering changes were incorporated to the Navitrack® THR CT-Free and OS Knee Universal predicates for the design of the proposed system according to the requirements for the placement of partial hip resurfacing components as compared to the total hip and total knee components of the predicates. The computer system and the tracking system were unchanged.
The proposed system was also compared to the Vectorvision Hip SR from Brainlab as a predicate and was found to have the same general intended use and indication for use, and utilizes the same main technology.

Performance Data:
Non-clinical tests were performed to assess that no new safety and efficacy issues were raised in the device. These included tests and analyses to verify that the accuracy and performance of the system was adequate for its intended use, equivalently as in the Navitrack® predicates.

Conclusion:
The information and data provided in this 510(k) Premarket Notification established that the Navitrack® System – Partial Hip Resurfacing Universal device is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Orthosoft, Inc.
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Regulatory Affairs & Quality
Management Director
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SEP 19 2007

Re: K071929
Trade/Device Name: Navitrack® Partial Hip Resurfacing – Universal
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 12, 2007
Received: July 13, 2007

Dear Mr. McLean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K071929

Device Name: Navitrack® Partial Hip Resurfacing – Universal

Indications for Use:

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Prescription Use ✓ OR Over-the-Counter Use _____
(per 21CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071929